



1651  
LAPG Rec'd PCT/PTO 20 APR 2006  
ATTORNEY DOCKET NO. 21101.0040U2  
PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of	)	
	)	
Kishore, <i>et al.</i>	)	Art Unit: 1651
	)	
Application No. 10/552,568	)	Examiner: Unassigned
	)	
Filing Date: October 11, 2005	)	Confirmation No. 2536
	)	
For: "COMPOSITIONS AND METHODS	)	
RELATED TO PRODUCTION OF	)	
ERYTHROPOIETIN"	)	

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

NEEDLE & ROSENBERG, P.C.  
Customer Number 23859

Sir:

Pursuant to the requirements of 37 C.F.R. § 1.56, submitted herewith on the accompanying Information Disclosure Statement List is a listing of documents known to Applicants and/or their attorneys. In accordance with 37 C.F.R. § 1.98(a)(2), copies of any cited U.S. patent or U.S. patent application publication documents are not enclosed. Copies of any cited foreign patent document and/or any non-patent publication are enclosed.

This Information Disclosure Statement is believed to be filed in a timely manner pursuant to 37 C.F.R. § 1.97(b)(3), in that a first Office Action on the merits of the present patent application has not yet been mailed to Applicants.

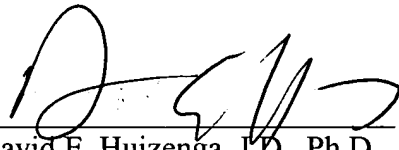
**ATTORNEY DOCKET NO. 21101.0040U2**  
**Application No. 10/552,568**

Consideration of the cited documents and making the same of record in the prosecution of the above-referenced application are respectfully requested.

No fee is believed due; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

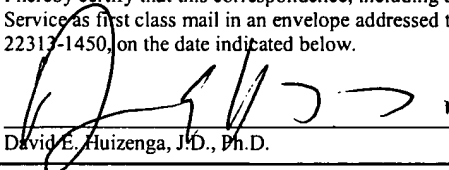
NEEDLE & ROSENBERG, P.C.

  
\_\_\_\_\_  
David E. Huizenga, J.D., Ph.D.  
Registration No. 49,026

NEEDLE & ROSENBERG, P.C.  
Customer Number 23859  
(678) 420-9300  
(678) 420-9301 (fax)

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8**

I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

  
\_\_\_\_\_  
David E. Huizenga, J.D., Ph.D.

  
\_\_\_\_\_  
Date

<b>INFORMATION DISCLOSURE STATEMENT LIST</b> (Use as many sheets as necessary)	Complete if Known	
	Application Number	10/552,568
	Filing Date	October 11, 2005
	First Named Inventor	Kishore, <i>et al.</i>
	Group Art Unit	1651
	Examiner Name	Unassigned

**U.S. PATENT DOCUMENTS**

Initials	Cite No.	Document No.	Date	Name	Class	Subclass	Filing Date (if appropriate)
	A1	4,526,888	July 2, 1985	Williams, <i>et al.</i>			
	A2	4,667,016	May 19, 1987	Lai, <i>et al.</i>			
	A3	4,703,008	October 27, 1987	Lin			
	A4	4,935,350	June 19, 1990	Patel, <i>et al.</i>			
	A5	4,987,121	January 22, 1991	Baertschi, <i>et al.</i>			
	A6	5,032,507	July 16, 1991	Yu, <i>et al.</i>			
	A7	5,104,653	April 14, 1002	Michalevich			
	A8	5,106,760	April 21, 1992	Egrie			
	A9	5,354,934	October 11, 1994	Pitt, <i>et al.</i>			
	A10	5,476,653	December 19, 1995	Pitt, <i>et al.</i>			
	A11	5,482,924	January 9, 1996	Royet, <i>et al.</i>			
	A12	5,547,933	August 20, 1996	Lin			
	A13	5,621,080	April 15, 1997	Lin			
	A14	5,618,698	April 8, 1997	Lin			
	A15	5,661,125	August 26, 1997	Strickland			
	A16	5,756,349	May 26, 1998	Lin			
	A17	5,830,705	November 3, 1998	Souza			
	A18	5,885,574	March 23, 1999	Elliott			
	A19	5,597,562	January 28, 1997	Nomura, <i>et al.</i>			
	A20	5,955,422	September 21, 1999	Lin			
	A21	6,221,397 B1	April 24, 2001	Russell-Jones, <i>et al.</i>			
	A22	6,319,499	November 20, 2001	Elliott			
	A23	6,784,154 B2	August 31, 2004	Westenfelder			

**FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Cite No.	Foreign Patent Document Country Code-NumAer-Kind Code	Date	Name	Translation Yes/No
	A24	WO 01/66149 A2	09/13/01	Valentis, Inc.	

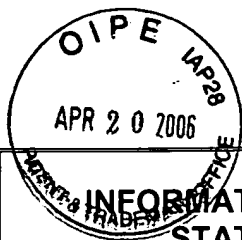
**NON-PATENT DOCUMENTS**

Examiner's Initials	Cite No.	Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication)
	A25	Abbate, M., <i>et al.</i> , "Proteinuria as a mediator of tubulointerstitial injury," Kidney Blood Press Res 22:37-46, 1999
	A26	Anagnostou, A., <i>et al.</i> , "Factors which affect erythropoiesis in partially nephrectomized and sham-operated rats," Blood 48:425-433, 1976

Examiner Signature:

Date Considered:

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

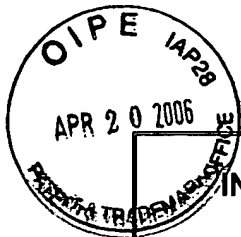


<b>INFORMATION DISCLOSURE STATEMENT LIST</b>  (Use as many sheets as necessary)	Complete if Known	
	Application Number	10/552,568
	Filing Date	October 11, 2005
	First Named Inventor	Kishore, <i>et al.</i>
	Group Art Unit	1651
	Examiner Name	Unassigned

**NON-PATENT DOCUMENTS**

Examiner's Initials	Cite No.	Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication)
	A27	Bachmann, S., <i>et al.</i> , "Co-localization of erythropoietin messenger RNA and ecto-5'-nucleotidase immunoreactivity in peritubular cells of rat renal cortex indicates that fibroblasts produce erythropoietin," J. Histochem Cytochem 41:335-341, 1993
	A28	Bellizzi, V., <i>et al.</i> , "The impact of early normalization of haematocrit by erythropoietin on renal damage in the remnant kidney model, Nephrol Dial. Transplant 13:2210-2215, 1998
	A29	Browne, <i>et al.</i> , "Erythropoietin: Gene cloning, protein structure, and biological properties," Cold Spring Harbor Symposia on Quantitative Biology, L1:693-702, 1986
	A30	Burton, C., <i>et al.</i> , "The role of proteinuria in the progression of chronic renal failure," Am. J. Kidney Dis. 27:765-775, 1996
	A31	Carlini, R., <i>et al.</i> , "Recombinant human erythropoietin stimulates angiogenesis in vitro," Kidney, Int. 47:740-745, 1995
	A32	Dendorfer, U., "Molecular biology of cytokines, Art. Organs," 20:437-444, 1996
	A33	Donnelly, S., "Why is erythropoietin made in the kidney? The kidney functions as a critmeter," Am J. Kidney Dis. 38:415-425, 2001
	A34	Eddy, A.A., "Interstitial nephritis induced by protein overload proteinuria," Am. J. Pathol. 135:719-733, 1989
	A35	Eddy, A.A., "Molecular basis of renal fibrosis," Pediatr. Nephrol. 15:290-301, 2000
	A36	Eddy, A.A., "Role of cellular infiltrates in response to proteinuria," Am. J. Kidney Dis., 37:S25-S29, 2001
	A37	Ferrara, N., "Molecular and biological properties of vascular endothelial growth factor, J. Mole. Med. 77:527-543, 1999
	A38	Gandi, R., <i>et al.</i> , "Immunolocalization of ecto-5'-nucleotidase in the kidney by a monoclonal antibody," Histochemistry 95:165-174, 1990
	A39	Ghielli, M., <i>et al.</i> , "Inflammatory cells in renal pathology," Néphrologie 19:59-67, 1998
	A40	Gleadle, J.M. <i>et al.</i> , "Induction of hypoxia-inducible factor-1 erythropoietin, vascular endothelial growth factor and glucose transporter-1 by hypoxia: evidence against a regulatory role for Src kinase," Blood 89:503-509, 1997
	A41	Ivan, M., <i>et al.</i> , "HIF alpha targeted for VHL-mediated destruction by proline hydroxylation: implications for O <sub>2</sub> sensing," Science 292:464-468, 2001
	A42	Jaakkola, P., <i>et al.</i> , "Targeting of HIF alpha to the von Hippel-Lindau ubiquitylation complex by O <sub>2</sub> regulated prolyl hydroxylation," Science 292:468-472, 2001
	A43	Jelkmann, W., "Erythropoietin: structure, control of production, and function," Physio. Rev. 72:449-489, 1992
	A44	Johnson, D.W., "Human renal fibroblasts modulate proximal tubule cell growth and transport via the IGF-1 axis," Kidney Int. 52:1486-1496, 1997
	A45	Kaissling, B., "Morphology of interstitial cells in the healthy kidney, Anat. Embryol. 193:303-318, 1996

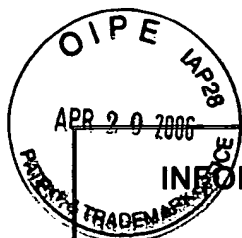
Examiner Signature:	Date Considered:
<b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	



<b>INFORMATION DISCLOSURE STATEMENT LIST</b>  (Use as many sheets as necessary)	Complete if Known	
	Application Number	10/552,568
	Filing Date	October 11, 2005
	First Named Inventor	Kishore, <i>et al.</i>
	Group Art Unit	1651
	Examiner Name	Unassigned

NON-PATENT DOCUMENTS		
Examiner's Initials	Cite No.	Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication)
	A46	Keane, W.F., "Proteinuria: its clinical importance and role in progressive renal disease, AM. J. Kidney Dis. 35:S97-S105, 2000
	A47	Kendall, R.G., "Erythropoietin," Clin. Lab. Hematol. 23:71-80, 2001
	A48	Kishore, B.K., "Mechanism of the thesaurismosis and altered lysosomal dynamics induced by poly-D-glutamic acid in kidney proximal tubular cells," Lab. Invest. 74:1025-1037, 1996
	A49	Kishore, B.K., <i>et al.</i> , "Expression of renal aquaporins 1, 2, and 3 in a rat model of cisplatin-induced polyuria," Kidney Int. 58:701-711, 2000
	A50	Kishore, B.K., <i>et al.</i> , "Mechanism of protection afforded by polyaspartic acid against gentamicin-induced phospholipidosis II. Comparative <i>in vitro</i> and <i>in vivo</i> studies with poly-L-aspartic, poly-L-glutamic and poly-D-glutamic acids," J. Pharmacol. Exp. Ther. 255:875-885, 1990
	A51	Kishore, B.K., <i>et al.</i> , "Poly-D-glutamic acid induces an acute lysosomal thesaurismosis of proximal tubules and a marked proliferation of interstitium in rat kidney," Lab. Invest. 74:1013-1023, 1996
	A52	Koury, S., <i>et al.</i> , "Localization of erythropoietin synthesizing cells in murine kidneys by in situ hybridization," Blood 71:524-527, 1988
	A53	Koury, S., <i>et al.</i> , "Quantitation of erythropoietin-producing cells in kidneys of mice by in situ hybridization. Correlation with hamtocris, renal erythropoietin mRNA and serum erythropoietin concentration," Blood 74:645-651, 1989
	A54	Krantz, S., "Erythropoietin," Blood 77:419-434, 1991
	A55	Lacombe, C., <i>et al.</i> , "The molecular biology of erythropoietin, Nephrol. Dial. Transplant 14:22-28, 1999
	A56	Lando, D.F., <i>et al.</i> , "Asparagine hydroxylation of HIF alpha transactivation domain: a hypoxic switch," Science 295:858-861, 2002
	A57	Le Hir, <i>et al.</i> , "Distribution of 5'-nucleotides in the renal interstitium of the rat," Cell Tissue Res. 258:177-182, 1989
	A58	Maxwell, <i>et al.</i> , "The interstitial response to renal injury: fibroblast-like cells show phenotypic changes and have reduced potential for erythropoietin gene expression, Kidney Int., 52:715-724, 1997
	A59	Maxwell, <i>et al.</i> , "Identification of the renal erythropoietin producing cells using transgenic mice," Kidney Int. 44:1149-1162, 1993
	A60	Priyadarshi, A., <i>et al.</i> , "Effects of reduction of renal mass on renal oxygen tension and erythropoietin production in the rat," Kidney Int. 61:542-546, 2002
	A61	Ribatti, D., "Human erythropoietin induces a pro-angiogenic phenotype in cultured endothelial cells and stimulates neovascularization <i>in vivo</i> ," Blood 93:2627-2636, 1999
	A62	Schena, F.P., "Cytokine network and resident renal cells in glomerular diseases. Nephrol. Dial. Transplant 14 [Suppl 1]:22-26, 1992
	A63	Schuster, S., <i>et al.</i> , "Cellular sites of extra renal and renal erythropoietin production in anaemic rats," Brit. J. Hemat. 81:153-159, 1992

Examiner Signature:	Date Considered:
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	



# **INFORMATION DISCLOSURE STATEMENT LIST**

(Use as many sheets as necessary)

Complete if Known

Application Number	<b>10/552,568</b>
Filing Date	<b>October 11, 2005</b>
First Named Inventor	<b>Kishore, et al.</b>
Group Art Unit	<b>1651</b>
Examiner Name	<b>Unassigned</b>

## **NON-PATENT DOCUMENTS**

Examiner's Initials	Cite No.	Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication)
	A64	Shih, S.C., et al., "Hypoxia-mediated regulation of gene expression in mammalian cells," Int. J. Exp. Pathol. 79:347-357, 1998
	A65	Todd, et al. Poly-L-Aspartic Acid Protects Cultured Human Proximal Tubule Cells Against Aminoglycoside-Induced Electrophysiological Alterations, Toxicology Lett. Vol. 90, Nos. 2 and 3:217-221, see Figures 1 and 2, 1997
	A66	von Kooten, C., et al., "Role of tubular cells in progressive renal disease," Kidney Blood Press. Res. 22:53-61, 1999
	A67	Westenfelder, C., "Unexpected renal actions of erythropoietin," Exp. Nephrol. 10:294-298, 2002
	A68	Westenfelder, C., et al., "Erythropoietin stimulates proliferation of human renal carcinoma cells," Kidney Int. 58:647-657, 2000
	A69	Westenfelder, C., et al., "Erythropoietin treatment ameliorates ischemic acute renal failure in rats by its anti-apoptotic, mitogenic and mitogenic actions, J. Am. Soc. Nephrol 12:793A, 2001
	A70	Westenfelder, C., et al., "Human, rat and mouse kidney cells express functional erythropoietin receptors," Kidney Int. 55:808-820, 1999
	A71	Westenfelder, C., et al., "Dual roles of NFkB in ischemic acute renal failure in rats: (1) mediates maladaptive suppression of erythropoietin (EPO) gene, (2) mediate EPO's anti-apoptotic effects in proximal tubular cells. Abstract #T323 accepted for presentation at the World Congress of Nephrology, Berlin, June 8-12, 2003
	A72	Wolf, G., et al., "Molecular mechanisms of tubulointerstitial hypertrophy and hyperplasia, Kidney Int. 39:401-420, 1991
	A73	Youssoufian, H., et al., "Structure, function, and activation of the erythropoietin receptor," Blood 81:2223-2236, 1993
	A74	Zoja, C., et al., "Protein overload activates proximal tubular cells to release vasoactive and inflammatory mediators," Exp. Nephrol. 7:420-428, 1999

Examiner Signature:

Date Considered:

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.